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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,132	08/22/2003	John B. Harley	OMRF 177 DIV	8887

32425 7590 08/15/2005

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EXAMINER

SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/646,132	Applicant(s) HARLEY ET AL	
	Examiner A R. Salimi	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 33-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/22/03</u> . | 6) <input type="checkbox"/> Other: _____ |

0-1

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III (claims 15-32) in the reply filed on 7/25/2005 is acknowledged.

Claims 1-14, 33-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups Election was made **without** traverse in the reply filed on 7/25/2005.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Please up-date the information by including the patent number.

Claim Rejections - 35 USC § 112

Claims 15-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of alleviating infection by Epstein-Barr virus, does not reasonably provide enablement for method of preventing infection by an Epstein-Barr virus. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The scope of the claims are directed to a vaccine against Epstein-Barr virus, Applicants have general statements regarding the vaccine composition and induction of protective response against Epstein-Barr virus which is a member of herpes virus and is known to latently infect a host. In addition, claims are directed to prevention in a host infected with HIV, which the host has depleted immune response. The field of vaccine development is generally considered unpredictable, and in particular herpesvirus vaccine field is unpredictable. To date there are no viable vaccines available against herpes virus or Epstein –Barr virus. The specification asserts induction of antibodies, which is not equivalent with long term protective response. The disclosure does not provide any challenge study or any data that would suggest method of prevention has been taught or achieved. One of ordinary skill in the art to be able to fully practice the invention would be forced to conduct large quantity of undue experimentation. The disclosure does not provide a working example that teaches prevention of Epstein-Barr virus in healthy host or a host infected with HIV or an autoimmune disease. Listing a laundry list of disorder is not equivalent to teaching. Regarding to an unpredictable field, this does not constitute an adequate disclosure. See *Fiers v. Revel* (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001-1007). For example, the CAFC stated that “It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement.” (See page 1005 of the decision). The disclosure must adequately guide the art worker to determine, without undue experimentation. In the

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instant case the specification does not teach or provide any guidance for development of a vaccine for preventing against Epstein-Barr virus infection. Applicants cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Murray et al (Journal of Exp. Medicine, July 1992, Vol. 176, pages 157-168).

Claims 15-19 are clearly anticipated by the above cited art. Murray et al taught a method of an extracellular component of Epstein-Barr virus expressed during latency. They expressed latent proteins such as LMP1 or LMP2 utilizing expression vector vaccinia (see the abstract, and

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Figure 1). In addition, they expressed the protein in a host cell (see Figure 2). Murray et al further disclosed induction of antibodies to the antigens (see the abstract).

Alternatively, it would have been obvious for one of ordinary skill in the art to utilize the product taught by Murray et al by modifying the method where the composition is administered prior to infection with Epstein-Barr virus, individual that previously had EBV infection, or administer the composition to individual that exhibits auto-immune symptoms. The modifications are seen as a design choice purview of one of skill in the art, unless the proof of criticality is proven. Therefore, the claimed invention is as a whole is prima facie obvious absent unexpected results.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

8/11/2005


ALI R. SALIMI
PRIMARY EXAMINER